UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
SOUTHEASTERN DIVISION

MICHELLE LAXTON,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	**No. 1:16-cv-193 SNLJ**
TEVA PHARMACEUTICALS USA, INC.,	)	
d/b/a GATE PHARMACEUTICALS, et al.	)	
	)	
Defendants.	)	

MEMORANDUM & ORDER

Plaintiff filed this lawsuit against defendant Teva Pharmaceuticals USA, Inc., d/b/a Gate Pharmaceuticals in circuit court in Cape Girardeau County, Missouri. Defendant removed the matter to this Court pursuant to this Court's diversity jurisdiction, 28 U.S.C. § 1332(a)(1). The lawsuit alleges that defendant Teva developed, manufactured, and marketed the prescription weight-loss drug Phentermine in its generic form and the brand name drug Adipex P. Plaintiff claims that defendant Teva failed to warn that Phentermine and Adipex P cause blood clots and that she was injured when she took these products. She claims Teva is liable for Failure to Warn and Design Defect (Count I) and in Strict Liability (Count II). After removal to this Court, plaintiff amended her complaint to add defendants the United States Food and Drug Administration ("FDA"), Commissioner of Food and Drugs Robert Califf in his official capacity, and Secretary of Health and Human Services Sylvia Matthews Burwell in her official capacity. Plaintiff added Count III against those defendants for a declaratory

judgment that FDA policies and procedures that prevent generic drug manufacturers from warning consumers about the risks of their products are arbitrary, capricious, unreasonable, and void as against public policy.

Defendant Teva has moved to dismiss plaintiff's complaint. The matter has been fully briefed and is now ready for disposition.

I. Legal Standard

The purpose of a Rule 12(b)(6) motion to dismiss for failure to state a claim is to test the legal sufficiency of a complaint so as to eliminate those actions "which are fatally flawed in their legal premises and deigned to fail, thereby sparing litigants the burden of unnecessary pretrial and trial activity." *Young v. City of St. Charles*, 244 F.3d 623, 627 (8th Cir. 2001) (citing *Neitzke v. Williams*, 490 U.S. 319, 326-27 (1989)). "To survive a motion to dismiss, a claim must be facially plausible, meaning that the 'factual content. . . allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Cole v. Homier Dist. Co., Inc.*, 599 F.3d 856, 861 (8th Cir. 2010) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

II. Discussion

Plaintiff's claims against Teva are based on two state-law theories of liability: (Count I) Teva's failure to warn of the purported effects of using the drugs phentermine and Adipex-P; and (Count II) Teva's alleged defective design of its phentermine and Adipex-P. Plaintiff admits that the Supreme Court of the United States has held that the makers of generic drugs may not be sued under state law for failing to warn customers about the risks associated with their products. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618

(2011); *see* #15 at ¶¶ 32, 36. Originally, a manufacturer seeking approval to market a new drug had to prove the drug was safe and effective and show that the proposed label was accurate and adequate. *Id.* at 612. The same rules applied to all drugs until 1984, when Congress allowed "generic drugs" to gain FDA approval by showing equivalence to a "brand-name" drug that had already been approved by the FDA. *Id.* For those generic drugs, a manufacturer had to show that its labeling was the same as labeling approved for the brand-name drug. *Id.* at 612-13. *Mensing* held that because generic drug manufacturers are required by federal law to use the same warning label as its name-brand counterpart, federal law preempted state laws that might otherwise require the manufacturer to label its drug to warn of product dangers. *Id.* at 618.

Plaintiffs suggest that Adipex-P is a brand name drug not subject to the *Mensing* holding. Indeed, the Supreme Court has held that state law tort claims may be made against brand-name drug manufacturers for failure to provide an adequate warning label. *Wyeth v. Levine*, 555 U.S. 555, 581 (2009). However, the Court may take judicial notice of FDA records that demonstrate Adipex-P is a generic drug for purposes of the *Mensing* holding.[1] The FDA records are conclusive. "Generic" drugs for the purposes of the *Mensing* holding are drugs that were approved by the FDA pursuant to an Abbreviated New Drug Application ("ANDA"). *See Mensing*, 564 U.S. at 612; *Caraco Pharm. Laboratories, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (explaining that a "a generic competitor" may file an ANDA that "piggy-back[s]" on the brand-name drug's earlier New Drug Application (" NDA")). Adipex-P, according to FDA records, has two

[1] "Generally, the Court must ignore materials that are outside of the pleadings, however, district courts 'may take judicial notice of public records and may thus consider them on a motion to dismiss.'" *Stahl v. United States Dept. of Agric.*, 327 F.3d 697, 700 (8th Cir. 2003); *see Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 984 (E.D. Mo. 2014) (taking judicial notice of FDA records and reports).

FDA approval numbers: the tablet is ANDA #085128; the capsule is ANDA #088023.[2] Both Adipex-P drugs, then, were approved pursuant to the Abbreviated New Drug application --- not the New Drug Applications used for brand name drugs subject to the *Wyeth* holding, 555 U.S. at 561. Adipex-P is a "generic" for purposes of the *Mensing* holding, and plaintiff cannot sue its manufacturer for matters regarding its labeling.

In Count III of her amended complaint, plaintiff seeks a declaratory judgment that the policies and procedures the FDA employs that prevent generic drug manufacturers from warning consumers adequately are arbitrary, capricious, unreasonable, and void as against public policy. (#15 at ¶ 35.) Because the defendant agency and related officials named in Count III have not yet responded to the Complaint (and their time for doing so has not expired), the Court will not address Count III at this time. Furthermore, because the disposition of Count III has bearing on the viability of Counts I and II, the Court will dismiss Counts I and II without prejudice.

As a result, the Court will grant defendant's motion in part as described above.

Accordingly,

IT IS HEREBY ORDERED that defendants' motion to dismiss (#23) is GRANTED in part.

Dated this 28th day of November, 2016.

STEPHEN N. LIMBAUGH, JR.
UNITED STATES DISTRICT JUDGE

[2] http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=085128; http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=088023 (last visited Nov. 23, 2016).